DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

NDA 000127

January 18, 2002

Haemonetics Corporation
Attention: Velda M. Hamilton
155 Medical Sciences Drive
Union, SC 29379

Dear Ms. Hamilton:

Please refer to your new drug application (NDA) dated January 21, 2000, received January 21, 2000, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Anticoagulant Citrate Phosphate Double Dextrose, for Additive Solution 3 (AS-3) in 250 mL polyvinyl chloride (PVC) bag, and for Additive Solution 3 (AS-3) in 300 mL polyvinyl chloride (PVC) bag.

We acknowledge receipt of your submission dated July 13, 2001 and received July 18, 2001. Your submission of July 13, 2001 constituted a complete response to our April 2, 2001 action letter.

We have completed our review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the immediate container labels submitted on January 10, 2002. Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA* (January 1999). (http://www.fda.gov/cder/guidance/2353fnl.pdf) Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but not more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 000127." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

If you have any questions, contact Richard Potter, Senior Regulatory Operations Officer, at 301-827-6156.

Sincerely, yours,

Mark Weinstein

Mark Weinstein, Ph.D.
Director
Division of Hematology
Office of Blood Research and Review
Center for Biologics
Evaluation and Research